

Blood Donor Competence, Autonomy, and Relatedness Enhancement

NCT02717338

Informed Consent Form

Parental Consent

11/01/18

Ohio University and New York Blood Center Parental Consent Form

Title of Research: Blood Donor CARE

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IRB number: OU 14-X-256; NYBC 818209

You are being asked to consent to your child taking part in research. For you to be able to decide if you want to permit this, you should understand what the project is about and the possible risks and benefits. This is known as informed consent. This form describes the purpose, procedures, possible benefits, and risks. It also explains how your child's personal information will be used and protected. Once you have read this form and your questions about the study are answered, you will be asked if you agree for your child to take part. We suggest that you print a copy of this form for yourself.

Summary of Study

This study is designed to help us better understand what leads to a good donation experience and increases willingness to give blood. Recent blood donors will be asked to complete two sets of surveys, several weeks apart, about their blood donation experience and attitudes. Between the two surveys, some donors will complete activities such as a short telephone call, viewing a donor website, and joining a close Facebook group for blood donors. We are interested in learning if these activities affect donor attitudes and behavior.

Explanation of Study

This study is being done to help us better understand what leads to a good donation experience and increases willingness to give blood. It will include 2240 first-time New York Blood Center donors.

The following steps describe what your child will be asked to do and how long your child's participation will last if you agree for your child to participate.

- 1) Begin by reading this form. If you have any questions, email Dr. Janis France at donorcare@ohio.edu.*
- 2) After reading this web page, if you agree for your child to take part in this study please provide your child's donor ID at the end of this form.*
- 3) Once we have both your child's assent and your consent, we will email your child a link to the study web site.*
- 4) When your child gets the web site link, they can complete the first survey*

about their thoughts and feelings about blood donation. If they do not complete the survey within a week we will email, text, or call to remind them.

5) After they complete the survey your child will be randomly assigned (like a coin toss) to one of eight groups. They may be asked to have a 10-15 minute phone call, review a blood donor web site for 10-15 minutes, and/or join a closed Facebook group for blood donors. If your child agrees, the phone call will be recorded for quality control, training, and communication of the research findings.

6) Five weeks after they complete the first survey your child will get an email with a link to the follow-up web site. These are the same questions that we asked the first time. We ask them again to see if thoughts or feelings have changed. If your child does not complete the second survey within a week we will email, text, or call to remind them.

7) One year after they complete the second survey we will contact your child by phone or email to ask if they donated blood since they took part in the study.

8) Also about one year after they complete the second survey we will use your child's donor ID code to see if they have donated blood with New York Blood Center since they took part in the study. We will also collect personal data (e.g., date of birth, height, weight, race/ethnicity) and donation details.

Additional information regarding this clinical trial is available from ClinicalTrials.gov using the study identifier (NCT number): NCT02717338.

Risks and Discomforts

There are no anticipated risks to taking part in this study. Your child will answer questions about themselves and their thoughts and feelings about blood donation. They may also take part in a phone call, review a web site, and/or join a Facebook group. The study is voluntary. Your child may stop at any time.

Benefits

This study is important to science and society by helping first-time blood donors decide if they wish to give blood again. Your child may benefit by getting information to help them meet their own donation goals and intentions.

Confidentiality and Records

Any information from this study that can identify your child will be kept confidential. The answers you give will be stored in password-protected files with no personally identifying information. All study data, including recorded phone calls, will be labelled using only a subject code. The master code list with names and contact information will be kept separately in a locked file cabinet in

the research office. The master code list and the phone recordings will be destroyed by January, 2020.

No person will be identified in any publications resulting from this project. Your child will not be identifiable in any public reports about the study. Information from the study will not be given to anyone except the research staff without your permission unless required by law.

While every effort will be made to keep your child's study information confidential, there may be instances where this information must be shared with:

- * Federal agencies such as the Office of Human Research Protections, whose responsibility is to protect human subjects in research, or the National Institutes of Health*
- * Representatives of Ohio University (OU), including the Institutional Review Board, a committee that oversees the research at OU.*

Compensation

Your child will get \$100 if they complete the first survey, any assigned task (phone call, web site review, join Facebook group), and the second survey. Your child will not get paid unless they complete all of their assigned steps. We will need your child's name and address to mail the check. Your child will get their check about one month after they complete the second survey.

Future Use Statement

Identifiers might be removed from data/samples collected, and after such removal, the data/samples may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Contact Information

If you have any questions about this study, please contact Dr. Chris France (donorcare@ohio.edu; 740-593-1079) or Dr. Janis France (donorcare@ohio.edu; 740-593-4557).

If you have any questions about your rights as a research participant, please contact Dr. Chris Hayhow (hayhow@ohio.edu; 740-593-0664), Director of Research Compliance, Ohio University.

By providing your child's donor ID below you agree that:

- You are 18 years of age or older.*
- You have read this form (or it has been read to you) and have been given the chance to ask questions and have them answered.*

- *You have been told of potential risks and they have been explained to your satisfaction.*
- *You understand Ohio University has no funds set aside for any injuries your child might receive as a result of taking part in this study.*
- *Your decision to permit your child to take part in this research is voluntary.*
- *Your child may leave the study at any time with no penalty. Your child will not lose any benefits to which they are otherwise entitled.*

*Your child's first and last name:*_____

*Your first and last name:*_____

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